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Pesticide and Environmental Toxicology Branch
Office of Environmental Health Hazard Assessment (OEHHA)
California Environmental Protection Agency
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Public comments on "OEHHA Proposed Revised Public Health Goal for Perchlorate"

Environmental Working Group (EWG) is a non-profit research and advocacy organization based in Washington, DC and Oakland, Calif. Our staff scientists conduct extensive research and analysis on an array of public health and environmental issues including chemical contamination of food, water, consumer products and the environment.

We are writing to express our strong support for the proposal by the Office of Environmental Health Hazard Assessment to lower the Public Health Goal (PHG) for perchlorate, a toxic component of rocket fuel that contaminates many drinking water supplies, from 6 parts per billion (ppb) to 1 ppb (OEHHA 2011).

OEHHA's proposal, announced in January 2011, is appropriate and overdue in light of the extensive body of evidence of perchlorate's adverse effects on thyroid hormone levels and the risks it poses to the health of the youngest Californians (Steinmaus 2010). Healthy thyroid hormone levels are crucial to normal brain development and growth *in utero* and in infants and young children (Trumbo 2010). Perchlorate exposure is ubiquitous in the United States and occurs primarily through ingestion of contaminated food and water (Blount 2010; Murray 2008). Since new data has shown that California current PHG is not adequately protective, setting the PHG for perchlorate at 1 ppb is a necessary step toward protecting the health of the state's residents, especially the most vulnerable populations.

EWG's technical comments focus on three major points:

- Latest research supports OEHHA's proposal to lower the PHG for perchlorate.
- EWG agrees with OEHHA's decision to use an uncertainty factor of 10 to account for the perchlorate risks to infants, the most vulnerable group.
- An even more protective PHG could be derived from, and would be supported by, currently available data such as the 2006 study by the Centers for Disease Control and Prevention.

Note that although EWG supports the goal proposed by OEHHA, we continue to disagree with the use of the Greer (2002) study as the basis for deriving the PHG. As outlined in section 3, the CDC study (Blount 2006a) is a more appropriate basis for perchlorate risk assessment.

Details and rationale for our comments are below:

1. Latest research supports OEHHA's proposal to lower the PHG for perchlorate.

The agency's decision to revise the public health goal for perchlorate in drinking water from 6 ppb to 1 ppb is strongly supported by the weight of evidence from recent scientific studies.

Notably, a 2006 study by the Centers for Disease Control and Prevention (CDC) demonstrated that exposure to perchlorate in drinking water at concentrations below 6 ppb poses a health risk to a sizable portion of the population. Researchers found that very low levels of perchlorate exposure were caused thyroid hormone disruptions in sensitive populations (Blount 2006a).

Also in 2006, the Massachusetts Department of Environmental Protection, using a weight-of-evidence approach, set a drinking water standard for perchlorate of 2 ppb, a level significantly lower than the current California PHG. The Massachusetts DEP scientists concluded "this value would reasonably minimize potential perchlorate exceedences attributable to chlorination, balancing perchlorate exposure and infectious disease control concerns" (Zewdie 2010). The Massachusetts drinking water standard was not based solely on health risks but took into consideration risk management decisions.

2. The risk assessment methodology was appropriate

2.1 Reevaluation of the population at greatest risk

Although other groups show increased susceptibility to perchlorate, the literature suggests that infants are particularly at high risk. Therefore, EWG supports the approach taken by OEHHA to base its proposed goal on the body weight and water consumption of infants, rather than of pregnant women, the subpopulation that forms the basis of the current California PHG set in 2004 (OEHHA 2004).

A 2010 peer-reviewed study published in the *Journal of Exposure Science & Environmental Epidemiology* suggests that perchlorate exposure "may be higher in infants compared with other persons due to diet (infant formula) and body weight versus intake considerations" (Schier 2010). The study assessed perchlorate contamination in powdered infant formulas and found it at concentrations ranging from 0.03-5.05 µg/L in all 15 brands of commercially available formulas tested. In 2000, the two most contaminated brands, made from cow's milk, accounted for 87 percent of the U.S. powdered formula market.

A 2007 collaborative study by the CDC and Boston University indicates that infants are routinely exposed to unsafe levels of perchlorate and documents that a major route of exposure is contaminated breast milk. The study examined breast milk samples from 49 Boston-area women and found that the median breast milk perchlorate level was 9.1 ppb (range 1.3-411 µg/L) (Pearce 2007). This is more than double the dose of perchlorate that the Environmental Protection Agency (EPA) considers safe; the most highly exposed babies ingested up to 10 times this amount.

Pearce (2007) also found that 47 percent of the babies tested were not getting adequate levels of iodine from breast milk. Since the effects of perchlorate are compounded by insufficient iodide consumption, these babies are at even greater risk of thyroid hormone disruption.

2.2 Re-evaluation of the uncertainty value used to derive the current PHG

EWG strongly supports the agency's decision to increase the uncertainty factor used to derive the proposed PHG. In 2004, the agency used an uncertainty factor of three in calculating the perchlorate PHG (OEHHA 2004), a very low value that fails to account for all the uncertainties inherent in the study methodology and specifically in the Greer study. In its 2011 proposal, the agency chose to increase the uncertainty factor to 10 (OEHHA 2011). Two factors support the choice of a higher uncertainty factor: the increased susceptibility of infants to perchlorate's thyroid toxicity, and the fact that the proposed PHG is based on a study of adults only. This improvement in the risk assessment will better protect the health of California children. However, as we note in section 3 below, there are additional limitations to the Greer study, such as small sample size and short study period, that have not been taken into account in choosing an uncertainty factor of 10. From a public health perspective, an uncertainty factor greater than 10 would likely be justified, which would lead to an even lower PHG for perchlorate in future.

2.3. Re-evaluation of drinking water consumption rates

EWG agrees with OEHHA's proposal to base the rates used in this draft report on both direct (i.e., from the tap) and indirect drinking water consumption (i.e., tap water added to make foods). The CDC findings demonstrated that mixing perchlorate-tainted formula powder with tap water containing "even minimal amounts" of the chemical could boost the resulting mixture's toxin content above the level the EPA considers safe (Schier 2010).

3. Alternative approaches

While EWG is fully supportive of the proposed PHG outlined in this draft document, we note that if the agency had considered alternative approaches in deriving the PHG, it could have developed an even more health-protective goal.

3.1. Use of the CDC study as the basis for deriving the PHG

One alternative approach would be the use of the 2006 CDC study, rather than the Greer study, as the basis for the calculation. We believe that the CDC study is particularly important because it includes:

> **A large, chronically exposed population** – The CDC study assessed effects of perchlorate exposure in 2,299 US residents ages 12 years and older. Perchlorate was detected in the urine of every participant (Blount 2006b).
>
> **A known vulnerable population** – The study population included more than 300 women of childbearing age with insufficient iodine intake, i.e. urinary iodine <100 µg/L (WHO

2004). According to Blount (2006a), since perchlorate acts as a competitive inhibitor of iodine uptake by the thyroid gland, "individuals with less iodine available to compete with perchlorate may be more vulnerable to impaired thyroid uptake."

Endpoints clearly indicative of adverse effects – The CDC study clearly showed an association between low levels of perchlorate exposure and concentrations of the thyroid hormones thyroxine (T4) and thyroid-stimulating hormone (TSH).

As outlined in this draft PHG document, the Greer study was based on the international dosing of a small population (N=37) of healthy adults for only two weeks, and the study lacked measurements of iodine status, which is known to be a critical variable (Greer 2002).

The short duration of the Greer study fails to account for the cumulative effect of longer-term exposure. A study in rats found greater perchlorate toxicity to the thyroid from 90-day exposure than from 14-day exposure (Springborn Laboratories 1998), suggesting that cumulative exposure may cause significant systemic injury that is not detectable in a short-term study. One longer-term (six month) human study with 13 volunteers has been promoted by industry as indicating that humans adapt to long-term exposure (Braverman 2006), but this study was unlikely to have adequate statistical power to detect an effect. This is particularly likely because we know from Blount (2006a) that some people are much more vulnerable to perchlorate toxicity than the average; women are more sensitive than men, iodine-deficient women are more sensitive than iodine-sufficient women, and iodine-deficient women with TSH levels on the high end of the normal range are even more sensitive.

In deriving this draft PHG, OEHHA considered an additional uncertainty factor of 3 to account for the short duration of the Greer study but ultimately decided against it, citing evidence that "iodine uptake is inhibited quickly after exposure begins and inhibition does not increase or increases only slightly as exposure continues."

California derived a "safe dose" of 0.37 µg/kg-day for perchlorate based on a statistical analysis of the Greer study data (benchmark dose low, defined as the 95 percent lower confidence limit for 5 percent inhibition of iodide uptake), divided by an uncertainty factor of 10 to account for inter-individual variability. Combined with a relative source contribution of 0.73 and exposure assumption data based on infants (body weight/water consumption rate), California proposes a PHG of 1 ppb. Since this calculation is based on the Greer study, it reflects some of the shortcomings of this study, described above. A calculation based on the CDC study would have resulted in a lower, more protective public health goal.

3.2. Use of a more appropriate value for relative source contribution (RSC) in light of evidence of greater exposure through food

OEHHA uses a relative source contribution (RSC) of 0.73 (or 73 percent) to represent the proportion of perchlorate that is ingested through drinking water. Current scientific literature indicates that the food supply may play a more important contribution to perchlorate contamination than this document suggests.

A recent study in the Journal of Exposure Science and Environmental Epidemiology suggests that food is the predominant source of perchlorate intake while drinking water is a much smaller contributor (Huber 2010). This study estimates that, for the total population and for women of child-bearing age, the perchlorate contribution from food is 86 percent while the contribution from water is only 14 percent. A calculation based on OEHHA's other assumptions but incorporating an RSC of 14 percent for drinking water, rather than 73 percent, would result in a PHG of 0.2 ppb.

Conclusion

In summary, EWG strongly supports of the proposed public health goal for perchlorate in drinking water of 1 ppb. We also find that the PHG proposed in this document is based on thorough scientific analysis and represents a middle-ground decision, since alternative approaches could have resulted in a lower value.

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